(i) locating an impermeable cover over the wound, said cover having a suction port;

(ii) providing a separate support to support said cover out of contact with the wound;

(iii) sealing the periphery of said impermeable cover to tissue surrounding the wound; and

E10 (iv) operably connecting said suction port with a vacuum system for producing said reduced pressure; and

(b) maintaining said reduced pressure until the wound has progressed toward a selected stage of healing comprising a cessation of partial thickness burn progression.

~~77~~ 38 (Amended Once) A method of treating a wound comprising the steps of:

(a) applying a reduced pressure to the wound, wherein said applying step comprises steps of:

(i) locating an impermeable cover over the wound, said cover having a suction port;

(ii) providing a separate support to support said cover out of contact with the wound;

(iii) sealing the periphery of said impermeable cover to tissue surrounding the wound; and

(iv) operably connecting said suction port with a vacuum system for producing said reduced pressure; and

(b) maintaining said reduced pressure until the wound has progressed toward a selected stage of healing comprising a reduction in bacterial density in the wound of at least 50%

REMARKS

Claims 38-41, 43-69, 71-80, 83-86, and 87-96 are pending in the application. The Examiner has allowed claims 79, 80 and 83-85. The Examiner has rejected claims 38-41, 44-47, 58-61, 66, 71-75 and 78. The Examiner has objected to claims 43, 48-57, 62-65, 67-69, 76 and 77 as being

dependent upon a rejected base claim but has indicated that such claims would be allowable if rewritten in independent form to include the subject matter of the base claim and any intervening claims. Applicants have rewritten claims 43, 48-50, 56, 62, 67, 69, 76, and 77 as suggested by the Examiner. The remaining claims to which the Examiner has rejected now depend from claims written in allowable dependent form.

Claim 86 has not been addressed in the Office Action; however, claim 86 depends from allowed claim 85 and thus Applicants assume that claim 86 is also allowed. Applicants have amended claims 38, 60, and 72 to more particularly claim Applicants' invention.

REJECTIONS UNDER 35 U.S.C. 102(b)

The Examiner has rejected claims 38-41, 44-47, 58-61, 66, 71-75 and 78 under 35 U.S.C. 102(b) as being anticipated by Thorn (GB 2195255) or Zamierowski. More than one Zamierowski patent has been disclosed by Applicants, and the Examiner has not identified which Zamierowski patent is being applied. Applicants assume that Examiner is applying US 4,969,880, since such patent includes a layer 250 mentioned by the Examiner.

The Examiner has stated that "Thorn discloses the claimed device ...having a cover, a seal, a reduced pressure means and a support means separate from the cover (7)" and that "the layer (7) would inherently hold the cover out of contact with wound." The Examiner has indicated that similar arguments apply with regard to the layer (250) of Zamierowski.

Applicants have amended independent claims 38, 60, and 72 to recite that the support means is configured to support the cover "out of contact with the wound without the support means contacting the wound." (Emphasis Added.) For example, as indicated in configurations Figs. 4-6 and the associated text, the support means does not make contact with the wound. Absence of contact between support means and the wound protects the wound site from impact or abrasion during treatment.

In contrast to Applicants' claimed invention for wound treatment, the disclosed method and apparatus of Thorn is wholly unrelated to treatment of a wound. Rather, Thorn relates to a "method and apparatus for vacuum treatment of an epidermal surface". (Emphasis Added.) Nowhere in Thorn is it disclosed or suggested that the method and apparatus of Thorn should be used in the treatment of a wound. Consistent with the goals and uses of the Thorn device, the layer 7 of Thorn lies "in contact with a part of the epidermal surface 3", not in contact with a wound.

(Thorn, p. 1, lines 116-117. Figs. 1-3. Emphasis Added.) Consequently, Thorn does not disclose each and every element recited in claim 72. For example, Thorn fails to disclose the following steps recited in claim 72: "(a) applying a reduced pressure to the wound...", "(i) locating an impermeable cover over the wound...", "(ii) providing a separate support to support said cover out of contact with the wound...", "(iii) sealing the periphery of said impermeable cover to tissue surrounding the wound", and "(b) maintaining said reduced pressure until the wound has progressed to a selected stage of healing."

With regard to Zamierowski, the intermediate material layer 250 is shown to contact the wound. (Figure 10.) The intermediate layer 250 is selected to have properties such as "(1) absorbency; (2) wicking or capillary action; and (3) surface contact action", indicating that the intermediate layer 250 functions to draw liquid away from the wound which requires the intermediate layer 250 to contact the wound. (Column 7, lines 47-50. Also, column 7, lines 52-column 8, line 27.) Modification of the Zamierowski layer 250 to avoid contact with the wound would render the layer 250 inoperable for the purpose of absorbing or wicking liquid away from the wound. Hence the layer 250 cannot be Applicants' claimed "support means separate from said cover configured for holding said cover out of contact with the wound without said support means contacting the wound" as recited in claims 38 and 60. In addition, Zamierowski fails to disclose several features recited in independent claims 38, 60 and 72.

Claims 38 and 60 recite the features of "an impermeable cover adapted to cover and enclose the wound and to maintain reduced pressure at the site of the wound" and "a seal operably connected with the cover for sealing said cover to tissue surrounding the wound." Claim 72 recites the steps of "sealing the periphery of said impermeable cover to tissue surrounding the wound" and "maintaining said reduced pressure until the wound has progressed toward a selected stage of healing." In contrast, the term "reduced pressure" is nowhere used within Zamierowski. To the contrary, Zamierowski provides at least three separate indications that reduced pressure is not created within the device of Zamierowski.

First, the membrane of Zamierowski is not sealed relative to atmospheric pressure. The relevant text of Zamierowski states that:

> The membrane perimeter 26 is pressed against the healthy skin 16 surrounding the wound site 12 to preferably form a relatively liquid-tight adhesive bond therebetween. (underlining added)(*Zamierowski, column 4, lines 65-68*).

A relatively liquid-tight bond as disclosed in Zamierowski is not an air-tight bond of the type needed to maintain reduced pressure at a wound site. While a relatively liquid-tight bond may be sufficient to retain some degree of liquid, it is not suited for maintaining reduced pressure at a wound site as claimed by Applicants and it is not Applicants' claimed seal of claims 38 and 60. Further, the above-quoted text of Zamierowski, reciting a relatively liquid-tight adhesive bond, must be considered in view of the figures of Zamierowski, which show air gaps at the perimeter.

Turning to the second reason, the figures of Zamierowski clearly show that the wound chamber 46 is not designed to be sealed with respect to atmospheric pressure. More specifically, Figures 1, 2, and 6 of Zamierowski show that the chamber 46 communicates with atmosphere through triangular air gaps formed between the two upturned edges 20 of the seam 21 of the covering material 22. (See Exhibit A.) This triangular air gap is most clearly illustrated in the side cross-sectional views of Figures 2 and 6 and in the side cross-sectional view of the alternate embodiment of Fig. 10. Figure 1 clearly shows that this triangular gap spans the entire length of the seam 21 to the outside perimeter 26 of the covering material. Thus, the membrane of Zamierowski is not sealed to atmosphere in the region of the triangular gap. As a result, the internal chamber 46 communicates with atmospheric pressure. Hence, the membrane of Zamierowski is not "an impermeable cover adapted to cover and enclose the wound and to maintain reduced pressure at the site of the wound" in the manner recited in claims 38 and 60. This air-gap structure disclosed in Zamierowski is consistent with the principle object of Zamierowski, which is <u>not</u> the treatment of a wound with reduced pressure, but is the evacuation of fluid from a wound.

Third, Zamierowski does not disclose a "reduced pressure supply means" for supplying and maintaining reduced pressure beneath the cover as recited in claims 38 and 60. A principal function and purpose of the wound dressing of Zamierowski is to drain liquids from a wound. In furtherance of that goal Zamierowski discloses an active evacuation mode of operation as follows:

> Alternatively, an active evacuation mode of operation involves attaching the tube 34 to the suction/vacuum source 42, whereby the fluid 20 is positively drawn from the wound site 12 and the chamber 46. (*Column 5, lines 44-48*)

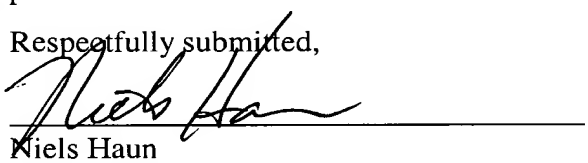
Action of a suction/vacuum source does not necessarily mean that reduced pressure will be formed at the site of the wound. Indeed, Zamierowski never states that reduced pressure is formed at the site of the wound. With the cover of Zamierowski being open to atmosphere through the triangular air gaps, negative pressure cannot be maintained within the wound chamber 12. Accordingly,

Zamierowski does not disclose the "reduced pressure supply means operably connected with the cover... [and] cooperating with said cover to supply and maintain said reduced pressure beneath the cover" as recited in claim 38. Similarly, Zamierowski does not disclose the "reduced pressure supply means operably connected with the cover ... for supplying and maintaining said reduced pressure to the wound" as recited in claim 60. Also, Zamierowski does not disclose the steps "applying a reduced pressure to the wound, wherein said applying step comprises steps of... (iii) sealing the periphery of said impermeable cover to tissue surrounding the wound; and (iv) operably connecting said suction port with a vacuum system for producing said reduced pressure; and (b) maintaining said reduced pressure until the wound has progressed toward a selected stage of healing" as recited in claim 72. Accordingly, Zamierowski fails to disclose the cover, seal, and vacuum source of claims 38 and 60, as well as the method of claim 72.

For the above reasons, Applicants respectfully request that the Examiner withdraw the rejections of claims 38-41, 44-47, 58-61, 66, 71-75 and 78.

In view of the foregoing amendments and remarks, it is believed that the claims in this application are now in condition for allowance. Early and favorable reconsideration is respectfully requested. The Examiner is invited to telephone the undersigned in the event that a telephone interview will advance prosecution of this application.

Respectfully submitted,



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ATTACHMENT

The following are the marked up copies of the claims as amended. Bracketed text has been deleted, and underlined text has been inserted.

38. (Amended Thrice) An appliance for administering a reduced pressure treatment to a wound comprising:

(a) an impermeable cover adapted to cover and enclose the wound and to maintain reduced pressure at the site of the wound;

(b) a seal operably connected with the cover for sealing said cover to tissue surrounding the wound;

(c) support means separate from said cover configured for holding said cover out of contact with the wound without said support means contacting the wound; and

(d) reduced pressure supply means operably connected with the cover for connection to a source of suction, said reduced pressure supply means cooperating with said cover to supply and maintain said reduced pressure beneath the cover.

43. (Amended Twice) [The appliance as recited in claim 38 wherein said seal includes] An appliance for administering a reduced pressure treatment to a wound comprising:

(a) an impermeable cover adapted to cover and enclose the wound and to maintain reduced pressure at the site of the wound;

(b) a seal operably connected with the cover for sealing said cover to tissue surrounding the wound, the seal including a cuff around the periphery of said cover for preventing said cover from digging into the skin during the treatment;

(c) support means separate from said cover for holding said cover out of contact with the wound; and

(d) reduced pressure supply means operably connected with the cover for connection to a source of suction, said reduced pressure supply means cooperating with said cover to supply and maintain said reduced pressure beneath the cover.

48. (Amended Once) [The appliance of Claim 47 wherein said] An appliance for administering a reduced pressure treatment to a wound comprising:

(a) an impermeable cover adapted to cover and enclose the wound and to maintain reduced pressure at the site of the wound, the cover comprising a flexible sheet;

(b) a seal operably connected with the cover for sealing said cover to tissue surrounding the wound;

(c) support means separate from said cover for holding said cover out of contact with the wound, wherein the support means connects with said sheet for supporting said sheet outward from the wound and wherein the support means comprises a support member located between said sheet and the wound, the support member [includes] including a porous cup member having a connection port for connecting with said reduced pressure supply means; and

(d) reduced pressure supply means operably connected with the cover for connection to a source of suction, said reduced pressure supply means cooperating with said cover to supply and maintain said reduced pressure beneath the cover.

49. (Amended Once) [The appliance of Claim 47 comprising] An appliance for administering a reduced pressure treatment to a wound comprising:

(a) an impermeable cover adapted to cover and enclose the wound and to maintain reduced pressure at the site of the wound, the cover comprising a flexible sheet;

(b) a seal operably connected with the cover for sealing said cover to tissue surrounding the wound;

(c) support means separate from said cover for holding said cover out of contact with the wound, wherein the support means connects with said sheet for supporting said sheet outward from the wound and wherein the support means comprises a support member located between said sheet and the wound;

(d) reduced pressure supply means operably connected with the cover for connection to a source of suction, said reduced pressure supply means cooperating with said cover to supply and maintain said reduced pressure beneath the cover; and

(e) a pad between the wound and said support member for alleviating discomfort caused in the wound by said support member.

50. (Amended Once) [The appliance of Claim 46 wherein said] An appliance for administering a reduced pressure treatment to a wound comprising:

(a) an impermeable cover adapted to cover and enclose the wound and to maintain reduced pressure at the site of the wound, the cover comprising a flexible sheet;

(b) a seal operably connected with the cover for sealing said cover to tissue surrounding the wound;

(c) support means separate from said cover for holding said cover out of contact with the wound, wherein the support means connects with said sheet for supporting said sheet outward from the wound and wherein the support means comprises a support member extending outwardly over the wound and external to said sheet; and

(d) reduced pressure supply means operably connected with the cover for connection to a source of suction, said reduced pressure supply means cooperating with said cover to supply and maintain said reduced pressure beneath the cover.

56. (Amended Once) [The appliance of Claim 47 wherein] An appliance for administering a reduced pressure treatment to a wound comprising:

(a) an impermeable cover adapted to cover and enclose the wound and to maintain reduced pressure at the site of the wound, the cover comprising a flexible sheet;

(b) a seal operably connected with the cover for sealing said cover to tissue surrounding the wound;

(c) support means separate from said cover for holding said cover out of contact with the wound, wherein

the support means connects with said sheet for supporting said sheet outward from the wound, the support means comprises a support member located between said sheet and the wound, and the support means includes a convex shield and wherein the flexible sheet overlies and extends beyond the shield at the periphery of the sheet; and

(d) reduced pressure supply means operably connected with the cover for connection to a source of suction, said reduced pressure supply means cooperating with said cover to supply and maintain said reduced pressure beneath the cover.

60. (Amended Thrice) An apparatus for treating a wound comprising:

(a) a vacuum system for producing a reduced pressure; and

(b) a reduced pressure appliance operably connected with said vacuum system for applying said reduced pressure to the wound, the appliance including:

(i) an impermeable cover adapted to cover and enclose the wound and to maintain reduced pressure at the site of the wound;

(ii) support means separate from said cover configured for holding said cover out of contact with the wound without said support means contacting the wound;

(iii) a seal operably connected with the cover for sealing said cover to tissue surrounding the wound; and

(iv) reduced pressure supply means operably connected with the cover for connection with the vacuum system for supplying and maintaining said reduced pressure to the wound.

62. (Amended Once) [The apparatus as recited in claim 61 wherein said] An apparatus for treating a wound comprising:

(a) a vacuum system for producing a reduced pressure, the vacuum system including a collection device for collecting fluid aspirated from the wound, the collection device [includes] including means for halting said application of reduced pressure to the wound when said fluid exceeds a predetermined quantity;

(b) a reduced pressure appliance operably connected with said vacuum system for applying said reduced pressure to the wound, the appliance including:

(i) an impermeable cover adapted to cover and enclose the wound and to maintain reduced pressure at the site of the wound;

(ii) support means separate from said cover for holding said cover out of contact with the wound;

(iii) a seal operably connected with the cover for sealing said cover to tissue surrounding the wound; and

(iv) reduced pressure supply means operably connected with the cover for connection with the vacuum system for supplying and maintaining said reduced pressure to the wound.

67. (Amended Once) [The apparatus of claim 60 wherein said] An apparatus for treating a wound comprising:

(a) a vacuum system for producing a reduced pressure comprising

(i) a vacuum pump connected with said tubing; and

(ii) a filter for preventing said pump from venting micro-organisms aspirated from the wound; and

(b) a reduced pressure appliance operably connected with said vacuum system for applying said reduced pressure to the wound, the appliance including:

(i) an impermeable cover adapted to cover and enclose the wound and to maintain reduced pressure at the site of the wound;

(ii) support means separate from said cover for holding said cover out of contact with the wound;

(iii) a seal operably connected with the cover for sealing said cover to tissue surrounding the wound; and

(iv) reduced pressure supply means operably connected with the cover for connection with the vacuum system for supplying and maintaining said reduced pressure to the wound, the reduced pressure supply means [comprises] comprising a length of tubing connected between said vacuum system and said cover. [and wherein said vacuum system comprises:

(a) a vacuum pump connected with said tubing; and

(b) a filter for preventing said pump from venting micro-organisms aspirated from the wound.]

69. (Amended Once) [The apparatus of claim 60 wherein said] An apparatus for treating a wound comprising:

(a) a vacuum system for producing a reduced pressure comprising [vacuum system comprises] control means for cyclically controlling said production of reduced pressure in alternating periods of production and non-production of reduced pressure; and

(b) a reduced pressure appliance operably connected with said vacuum system for applying said reduced pressure to the wound, the appliance including:

(i) an impermeable cover adapted to cover and enclose the wound and to maintain reduced pressure at the site of the wound;

(ii) support means separate from said cover for holding said cover out of contact with the wound;

(iii) a seal operably connected with the cover for sealing said cover to tissue surrounding the wound; and

(iv) reduced pressure supply means operably connected with the cover for connection with the vacuum system for supplying and maintaining said reduced pressure to the wound.

72. (Amended Twice) A method of treating a wound comprising the steps of:

(a) applying a reduced pressure to the wound, wherein said applying step comprises steps of:

(i) locating an impermeable cover over the wound, said cover having a suction port;

(ii) providing a separate support to support said cover out of contact with the wound without said support means contacting the wound;

(iii) sealing the periphery of said impermeable cover to tissue surrounding the wound; and

(iv) operably connecting said suction port with a vacuum system for producing said reduced pressure; and

(b) maintaining said reduced pressure until the wound has progressed toward a selected stage of healing.

76. (Amended Once) [The method of claim 72 wherein said] A method of treating a wound comprising the steps of:

(a) applying a reduced pressure to the wound, wherein said applying step comprises steps of:

(i) locating an impermeable cover over the wound, said cover having a suction port;

(ii) providing a separate support to support said cover out of contact with the wound;

(iii) sealing the periphery of said impermeable cover to tissue surrounding the wound; and

(iv) operably connecting said suction port with a vacuum system for producing said reduced pressure; and

(b) maintaining said reduced pressure until the wound has progressed toward a selected stage of healing comprising a [selected stage of healing is] cessation of partial thickness burn progression.

77.(Amended Once) [The method of claim 72 wherein said] A method of treating a wound comprising the steps of:

(a) applying a reduced pressure to the wound, wherein said applying step comprises steps of:

(i) locating an impermeable cover over the wound, said cover having a suction port;

(ii) providing a separate support to support said cover out of contact with the wound;

(iii) sealing the periphery of said impermeable cover to tissue surrounding the wound; and

(iv) operably connecting said suction port with a vacuum system for producing said reduced pressure; and

(b) maintaining said reduced pressure until the wound has progressed toward a selected stage of healing comprising [selected stage of healing is] a reduction in bacterial density in the wound of at least 50%

Exhibit A

Fig.1.

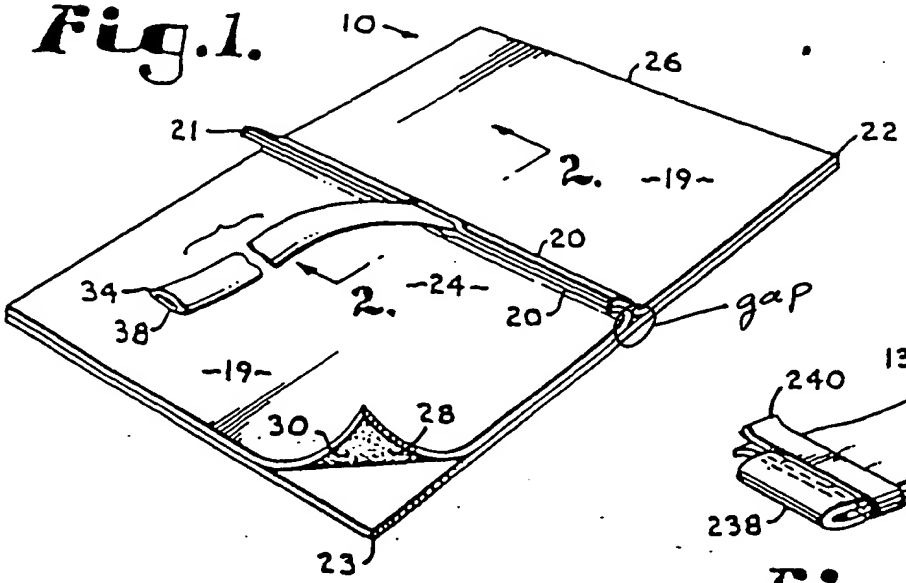

Fig.5.

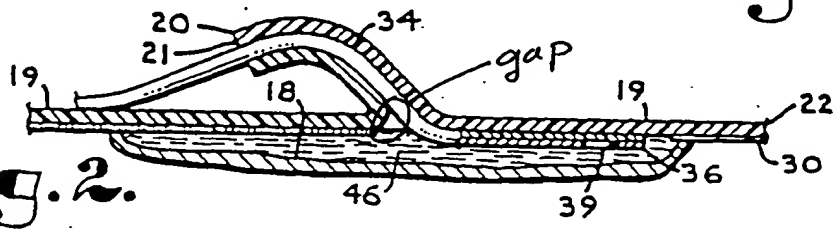

Fig.2.

Fig.3.

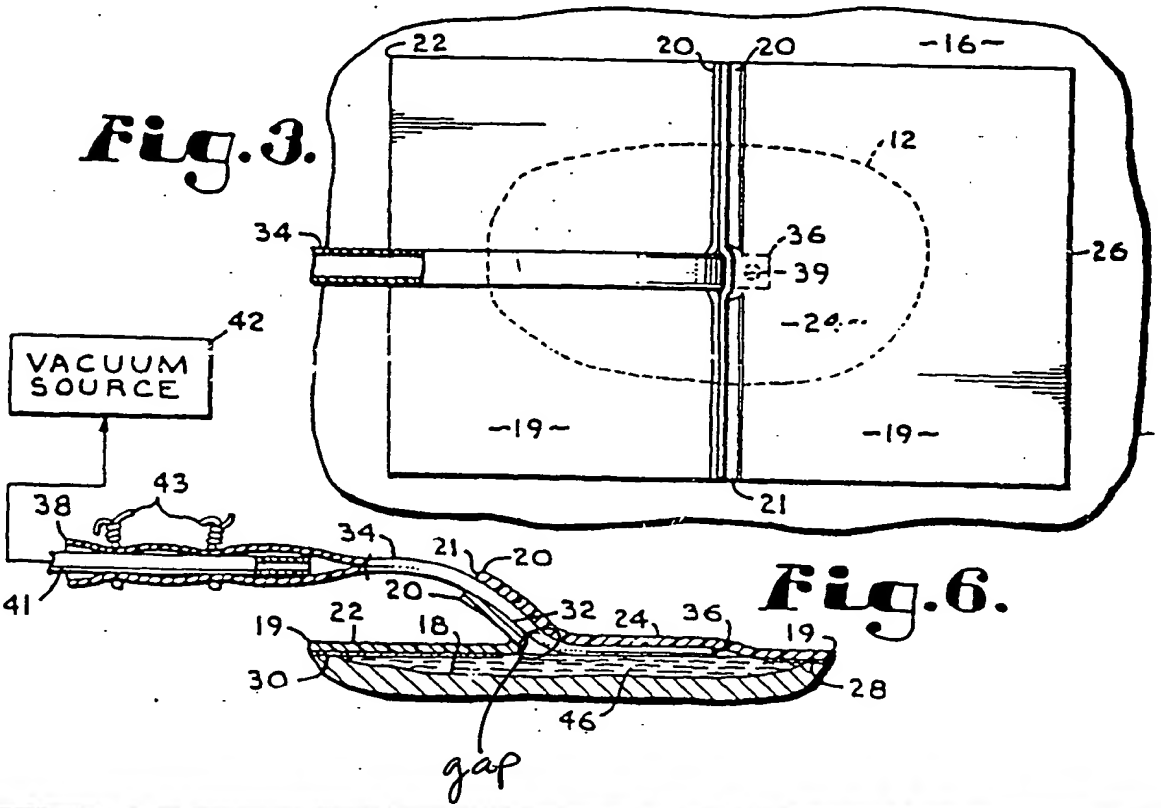

Fig.6.